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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/458,354	12/09/1999	STEPHEN G. SCHAILBLE	ACSC-60419	8755

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[REDACTED] ART UNIT

[REDACTED] PAPER NUMBER

3763

DATE MAILED: 10/23/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/458,354	SCHAIBLE ET AL. <i>DV</i>
	Examiner Michael M. Thompson	Art Unit 3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 23 July 2002.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 8-21 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 8-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kume et al. (5,411,016) in view of Muni et al. (5,316,706). Kume et al. teaches an intraluminal balloon catheter having an elongated catheter shaft that is substantially transparent formed of a polymeric material. He teaches an inflatable member in communication with an inflation lumen. Kume et al. further teaches an outer diameter that is about 0.7 mm. Kume et al. further teaches that the balloon can either be transparent or non-transparent and further teaches different materials that may comprise a balloon made from a different polymer. It is clear that Kume et al. states that it is contemplated that any suitable polymeric materials may be used in the construction of the device. Kume et al. teaches all of the limitations of the claims except for explicitly reciting the device being constructed of an amorphous polymeric material such as polyetheretherketone (PEEK) of a crystallinity not greater than 20%, an outer diameter of about 0.05 to about 0.13, or one portion of the shaft being constructed of PEEK and the other section being constructed of another polymeric material. Muni et al. teaches a catheter formed of an amorphous material such as PEEK wherein a portion of the catheter is more crystalline than another portion to provide different flexibilities. He teaches a crystallinity of about 20% to provide a difference in stiffness. It would have been obvious to one having ordinary skill in the art, at the time the invention was

made to have modified the balloon catheter device of Kume et al. with the amorphous PEEK transparent material and all of the inherent properties of PEEK for the purpose of increasing stiffness, kink resistance, enhanced thermal and electrical conductance, and increased resistance to chemicals while reducing permeability to gasses. Please note that it is the Examiner's position that an outer diameter of about 0.05 to 0.13 is merely an obvious design choice and the transmittance of visible light from about 50% to 100% is considered an inherent property of amorphous polyetheretherketone.

Response to Arguments

3. Applicant's arguments filed 07-23-02 have been fully considered but they are not persuasive. The Examiner respectfully disagrees with Applicant's interpretation of the instant rejection. It is the Examiner's position that the claims in the rejection under 35 USC § 103(a) Kume et al. clearly teaches that any optically transparent polymer may be used in the construction of his catheter. Kume et al. was only deficient in teaching that the device was made of Polyetheretherketone (PEEK). Therefore, in the least, it was the Examiner's position that PEEK was simply a material that was capable of being used in a transparent form usually found in thin films. Regardless, contrary to Applicant's assertion that Muni et al. fails to teach a transparent form of PEEK Muni et al. in fact does teach a transparent form of PEEK. While Applicant acknowledges that Muni et al. teaches both an amorphous state and a state of high crystallinity, Applicant appears to dismiss the PEEK taught by Muni et al. as being transparent as there are "other factors" that have "significant impact to the extent that PEEK is not necessarily transparent." While the teaching of transparency by Muni et al. may not necessarily be relied upon in the combination of Kume and Muni et al., it is the Examiner's position that in fact Muni

et al. does teach a transparent form of PEEK. Muni et al. is in fact teaching a transparent form of PEEK upon closer review of the first Example in column 4. In lines 55-68 Muni et al. clearly states that the materials can be substituted in the example. More notably, the materials listed above in lines 29-40 are inherently primary candidates for modification of the amorphous PET tubing. It is well known that PEEK in the form of a film is a polymer that is amorphous and transparent. Muni et al. further teaches that the dimensions, temperature, heating time, and heating method may vary in order to achieve the novel characteristics of the invention which is, in the least, is an amorphous state of PEEK producing the highest form of crystallization (or purification). In the least, Applicant's own specification clearly admits that there are transparent forms of PEEK. While it is the Examiner's position that Kume et al. teaches using a transparent form of any polymer that can take the form of transparency and the rejection may not necessarily rely upon Muni et al. explicitly teaching transparency, it is also the Examiner's position that Muni et al. obviously teaches that a form of transparent PEEK may be used given the level of ordinary skill in the art. With respect to claim 13, it is the Examiner's position that the transparent portion of Kume et al. (35) is "near" the proximal end. Therefore, the instant application has been made Final.

Conclusion

4. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contacts

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Michael Thompson whose telephone number is (703) 305-1619. The Examiner can normally be reached on Monday through Friday from 9 am to 5 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Primary, AnhTuan Nguyen, can be reached on (703) 308-2154. The official fax phone number for submissions to the organization where this application or proceeding is assigned is (703) 872-9302. The official fax phone number for submission of After Final response is (703) 872-9303.

Michael M. Thompson

Patent Examiner



MICHAEL J. HAYES
PRIMARY EXAMINER

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October 18, 2002